Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472309	11/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Harmon Memorial Hospital	400 East Chestnut, Hollis, OK	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 11/17,18/2020. The findings were reviewed with the laboratory director, laboratory supervisor, director of nursing, and the chief accounting officer during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to review and evaluate proficiency testing results for 2 of 28 events. Findings include: (1) On 11/17/2020, surveyor #2 reviewed 2019 and 2020 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2019 Chemistry Core (i) Chloride - 3 of 5 results exhibited a negative bias (aa) Sample CH-07- SDI of -2.1 (bb) Sample CH-08 - SDI of -2.3 (cc) Sample CH-10 - SDI of -2.4 (b) Second 2020 Chemistry Core (i) CK-MB - 4 of 5 results exhibited a positive bias (aa) Sample CH-06- SDI of 2.1 (bb) Sample CH-07 - SDI of 2.1 (cc) Sample CH-08 - SDI of 2.1 (dd) Sample CH-10 - SDI of 2.1 (2) Surveyor #2 could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with laboratory supervisor. The laboratory supervisor stated on 11/17/2020 at 03: 40 pm the biases had not been addressed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with the interim laboratory manager, the laboratory failed to have written procedures that explained the current practices and procedures being performed in the laboratory. Findings include: (1) On 11/17/2020, surveyor #1 reviewed the procedure manual titled, "Policies and Procedures Manual Volume 2" which contained a written KOH (Potassium Hydroxide) procedure; (2) Surveyor #1 asked the interim laboratory manager if KOH testing was performed in the laboratory. The interim laboratory manger stated to surveyor #1 on 11/17/2020 at 11:00 am, the laboratory did not perform KOH testing and the procedure should not be in the procedure manual.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer instructions, and interview with the interim laboratory manager, the laboratory failed to follow the manufacturer's instructions for Procalcitonin for 1 of 3 patients. Findings include: (1) On 11/17/2020 at 10:30 am, the interim laboratory manager stated to surveyor #1 Procalcitonin testing was performed on the Mini Vidas analyzer, using the B'R'A'H'M'S PCT assay; (2) On 11/18/2020, surveyor #1 reviewed the package insert for the assay. The section titled "Intended Use" stated, "Used in conjunction with other laboratory findings and clinical assessments, Vidas B'R'A'H'M'S PCT is intended for use to aid in the to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock."; (3) Survyeor #1 reviewed 3 patient Procalcitonin records which confirmed the laboratory had not followed the manufacturer's intended use. The assay had been used on 1 patient that was not critically ill (testing had been performed on 11/06,07,08/2020). The patient was seen in the emergency room on 11/05/2020 for abdominal pain and admitted to the hospital in stable condition. The patient was not admitted to the ICU and there was no indication in the records the patient was critically ill; (4) Surveyor #1 reviewed the records with the interim laboratory manager, who stated on 11/18/2020 at 10:35 am, the testing had been performed on a patient that was not critically ill.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a

	function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the interim laboratory manager, the laboratory failed to ensure the urine centrifuge was functioning properly for 1 of 2 function checks. Findings include: (1) On 11/17/2020 10:30 am, the interim laboratory manager stated the following to surveyor #1: (a) Urine sediment examinations were performed in the laboratory; (b) The specimens were processed in the Unico Power Spin LX Centrifuge at a speed of 2000 rpm (revolutions per minute) for 5 minutes. (2) Surveyor #1 reviewed the policy titled, "Centrifuge Policy", which required that speed and timer checks be performed annually; (3) Surveyor #1 reviewed the speed and timer checks performed in 2019 and to date in 2020. The records showed the timer had not been checked at the time the urine specimens were processed, to ensure the centrifuge was functioning properly at that time, for 1 of 2 checks performed as follows: (a) 07/29/2020 - The timer had been checked at 10 minutes. (4) Survyeor #1 reviewed the findings with the interim laboratory manager, who stated on 11/17/2020 at 2:10 pm, the centrifuge timer had not been checked at the time used to process urine specimens.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the interim laboratory manager, the laboratory failed to follow the manufacturer's specifications for establishing quality control ranges for PT/INR testing for 2 of 2 lot numbers. Findings include: (1) On 11/18/2020 at 10:30 am the interim laboratory manager stated the following to surveyor #1: (a) The Hemochron Jr. Signature + analyzer was used to perform testing for PT (Prothrombin Time)/ INR (International Normalized Ratio) testing using the Citrate PT cuvettes; (b) Normal and abnormal controls were tested each 30 days and with new lot numbers of cuvettes. (2) Surveyor #1 reviewed the manufacturer's instructions (package inserts) for the control materials which stated, "Accriva recommends that each institution establish its own expected range of response based on the mean +/- 2 standard deviations of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range. Studies show that intra-laboratory variation in test results should produce a coefficient of variation of approximately 14% or less for coagulation control tests"; (3) Surveyor #1 then reviewed quality control records for lot changes performed in August 2020. For 2 of 2 lot numbers of quality control testing, there was no evidence the laboratory had followed the manufacturer's instructions for ensuring the intra-laboratory variation in test results produced a coefficient of variation (CV) of 14% or less. The laboratory did not calculate the %

	CV for the following lot numbers which were put into use on 08/21/2020: (a) Normal Control Lot #A0DNC001 (b) Abnormal Control Lot #J9DAC011 (4) Surveyor #1 reviewed the findings with the interim laboratory manager who stated on 11/18/2020 at 2:10 pm, the laboratory did not calculate the %CV to ensure it was 14% or less.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the interim laboratory manager, the laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of testing. Findings include: (1) On 11/17/2020 at 9:45 am, the interim laboratory manager stated to the following to surveyor #1: (a) The laboratory performed Blood Gas (pH, pCO2, pO2) testing Osmetech OPTI CCA analyzer; (b) Two levels of quality control (QC) materials were performed each 8 hours of patient testing. (3) On 11/19/2020 surveyor #1 reviewed QC and patient testing records from 02/10/2020 through 09/24/2020. The review showed that QC testing had not been performed each eight hours of patient testing for 5 of 6 patients tested. It was identified that QC was tested after patient testing: (a) Patient tested on 02 /10/2020 with results reported at 10:05 am (i) Level 1 and level 3 QC had not been performed after 01/29/2020 at 09:44 am (ii) Level 1 and level 3 QC had not been performed until 02/10/2020 at 10:24 am (b) Patient tested on 02/11/2020 with results reported at 01:59 pm (i) Level 1 and level 3 QC had not been performed after 02/10 /2020 at 10:24 am (ii) Level 1 and level 3 QC had not been performed until 02/11 /2020 at 02:27 pm (c) Patient tested on 02/17/2020 with results reported at 02:08 pm (i) Level 1 and level 3 QC had not been performed after 02/11/2020 at 02:27 pm (ii) Level 1 and level 3 QC had not been performed until 02/17/2020 at 02:20 pm (d) Patient tested on 09/16/2020 with results reported at 01:16 pm (i) Level 1 and level 3 QC had not been performed after 08/27/2020 at 03:42 pm (ii) Level 1 and level 3 QC had not been performed until 09/16/2020 at 01:50 pm (e) Patient tested on 09/22/2020 with results reported at 05:35 pm (i) Level 1 and level 3 QC had not been performed after 09/16/2020 at 01:50 pm (ii) Level 1 and level 3 QC had not been performed until 09/22/2020 at 05:53 pm (f) Patient tested on 09/24/2020 with results reported at 08:22 am (i) Level 1 and level 3 QC had not been performed after 09/22/2020 at 05:53 pm (ii) Level 1 and level 3 QC had not been performed until 09/24/2020 at 08:44 am (3) Surveyor #1 reviewed the records with the interim laboratory manager who stated on 11/18/2020 at 11:25 am QC was being performed after patient testing and not each 8 hours of patient testing.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 2 of 5 competency evaluations performed; Findings include: COMPETENCY EVALUATION (1) On 11/17/2020, surveyor #2 reviewed records for 5 persons performing moderate complexity testing in 2019 and 2020. The records showed the evaluations for 2 of 5 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing

	Person #3 - The 12/03/2019 evaluation had been performed by the laboratory supervisor (this person had earned a bachelors degree in clinical laboratory science but did not have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible); (b) Testing Person #4 - The 10/28/2020 evaluation had been performed by the laboratory supervisor. (2) Surveyor #2 explained to the laboratory supervisor that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory supervisor stated to the surveyor on 11/17/2020 at 12:30 pm, the evaluations had been performed by an individual who did not meet the years of experience of a technical consultant. PROFICIENCY TESTING ATTESTATION FORMS (1) On 08/19/2021, the surveyor reviewed 2020 and 2021 proficiency testing records and identified that 1 of 7 attestation statements had been signed by an individual who did not meet the minimal educational qualifications of a technical consultant or designee. The attestation statement had been signed by the laboratory coordinator (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The following attestation statement had been signed by the laboratory coordinator: (a) First 2021 Chemistry Core Event (2) The surveyor reviewed the records with the laboratory coordinator. On 08/19/2021 at 12:25 pm, the laboratory coordinator stated the attestation statement, as indicated above, had been signed and dated by an individual who did not meet the regulatory qualification requirements of a technical consultant or designee.